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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,289	08/14/2006	Tomoyuki Tahara	081356-0248	1968

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FOLEY AND LARDNER LLP  
SUITE 500  
3000 K STREET NW  
WASHINGTON, DC 20007

EXAMINER
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OGUNBIYI, OLUWATOSIN A

ART UNIT	PAPER NUMBER
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1645

MAIL DATE	DELIVERY MODE
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10/18/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/549,289	TAHARA ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Oluwatosin Ogunbiyi	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-65 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-65 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____                                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____   | 6) <input type="checkbox"/> Other: ____                           |

### DETAILED ACTION

Claims 1-65 are pending in the application.

#### Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- I. Group I, claim(s) 1-47, 49,54,55,60 and 61 drawn to an antibody binding to a 40 kDa OMP or a functional fragment thereof, which has activity of inhibiting the binding of hemin to 40 kDa OMP and an antibody binding to a 40 kDa OMP or a functional fragment thereof, which is produced by a hybridoma h13-17 (accession No. FERM BP- 8325), hybridoma 5-89-2 (accession No. FERM BP- 8323) and hybridoma a44-1 (accession No. 8324).
- II. Group II, claim(s) 48, 50-53 drawn to a nucleic acid, which is possessed by a hybridoma h13-17, a44-1 and 5-89-2 and an expression vector which has said nucleic acid and a host which has said expression vector and a method of producing an antibody to 40 –kDa OMP.
- III. Group III, claim(s) 56,58,62 and 63 drawn to use of an antibody binding to 40 kDa OMP for the production of an agent for suppressing alveolar bone resorption, which comprises isolating a gene that encodes an antibody binding to 40 kDa OMP from a hybridoma h13-17, a44-1 and 5-89-2.

- IV. Group IV, claim(s) 57,59,64 and 65 is drawn to a method for suppressing alveolar bone resorption and a method for diagnosing, preventing or treating periodontal diseases comprising preparing an antibody binding to 40 kDa OMP or a functional fragment thereof and administering the antibody or the fragment to an animal and a method for suppressing alveolar bone resorption and a method for diagnosing, preventing or treating periodontal diseases comprising preparing an antibody binding to 40 kDa OMP or a functional fragment thereof and administering the antibody or the fragment to an animal wherein said antibody is produced by hybridoma h13-17, a44-1 and 5-89-2.

The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

- The technical feature of Groups I is an antibody binding to 40 kDa OMP or a functional fragment thereof.
- The technical feature of Group II is the nucleic acid that encodes an antibody containing a variable region of an antibody produced by the hybridomas a44-1, h13-17 and 5-89-2.
- The technical feature of Group III is the method for making an agent for suppressing alveolar bone resorption and a method for diagnosing, preventing or treating periodontal diseases comprising using an antibody binding to 40 kDa OMP or a functional fragment thereof.
- The technical feature of Group IV is the method for suppressing alveolar bone resorption and a method for diagnosing, preventing or treating periodontal diseases by preparing an antibody binding to 40kDa OMP or functional fragment thereof and administering the antibody or the fragment to an animal.

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Group I lacks unity with Group II-IV, because the technical feature of Group I is anticipated by the art (Abiko et al. Infection and Immunity Sept. 1997, p.3966-3969) and therefore not "special" within the meaning of PCT Rule 13.2 because it does not provide for a contribution that the claimed invention makes over the art. Abiko et al teaches an antibody against 40 kDa OMP (see abstract).

This application contains claims directed to more than one species of the generic invention.

The species are as follows for Groups I-IV

Species of antibody, which have the activity, selected from the following:

1. activity of inhibiting the binding of hemin to 40-kDa OMP
2. activity of inhibiting the coaggregation of *P. gingivalis* and activity of promoting human neutrophilic phagocytosis
3. activity of inhibiting the coaggregation of *P. gingivalis* and activity of inhibiting the binding of hemin to 40-kDa OMP.
4. activity of promoting human neutrophilic phagocytosis and activity of inhibiting the binding of hemin to 40-kDa OMP.
5. activity of inhibiting the coaggregation of *P. gingivalis*, (2) activity of promoting human neutrophilic phagocytosis, and (3) activity of inhibiting the binding of hemin to 40-kDa OMP.

These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. Each of the antibody species listed above have a different technical feature as defined by the function of each specie. For example, species 3 has the technical feature of the activity of inhibiting both coaggregation *P. gingivalis* and activity of inhibiting the binding of hemin

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to 40-kDa OMP while antibody species 2 has the technical feature of the activity of inhibiting the coaggregation of *P. gingivalis* and activity of promoting human neutrophilic phagocytosis. Each of the antibody species as a specific defined function/activity as recited in the claims and thus lack a common technical feature.

Applicant is required, in reply to this action, to elect a single species of antibody as listed above to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions

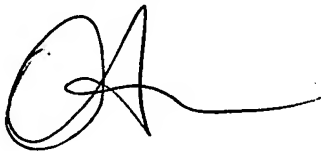
unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103 (a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Oluwatosin Ogunbiyi whose telephone number is 571-272-9939. The examiner can normally be reached on M-F 7am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campbell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Oluwatosin Ogunbiyi  
Patent Examiner  
Art unit, 1645

  
**PATRICIA A. DUFFY**  
**PRIMARY EXAMINER**

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